Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 15, 1998 list were made in February, 1998

New Approvals

ANADA Number: 200-226

Pioneer Product:	042-427
Trade Name :	Tricaine-S
Ingredients:	Tricaine methanesulfonate
Sponsor:	Western Chemical, Inc.
Approval Date:	11/21/97
Status:	Over-the-counter
Route:	Immersion of animal in water
Species:	Fish and cold-blooded animals
Drug Form:	Powder
Concentration:	3.5 oz. and 2.2 lbs (2 g/5 gallons of water yield a concentration of 100 mg/L)
Indications:	For anesthesia and tranquilization of fishes and other cold-blooded animals.
Withdrawal:	Do not use within 21 days of harvesting fish for food.

21CFR 529.2503

ANADA Number: 200-237

Pioneer Product:	135-773
Trade Name :	Isoflurane, USP
Ingredients:	Isoflurane
Sponsor:	Rhone-Poulenc Chemicals, Ltd.
Approval Date:	12/19/97
Status:	Prescription only
Route:	Inhalation
Species:	Equine, canine
Drug Form:	Liquid
Concentration:	99.9%
Indications:	For induction and maintenance of general anesthesia in horses and dogs.

21CFR 529.1186

NADA Number: 141-096

Trade Name :	Dicural[â] Tablets
Ingredients:	Difloxacin hydrochloride
Sponsor:	Fort Dodge Animal Health
Approval Date:	11/20/97
Status:	Prescription only
Route:	Oral
Species:	Canine
Drug Form:	Tablets
Concentration:	11.4, 45.4, and 136 mg/tablet
Indications:	For the management of diseases in dogs associated with bacteria susceptible to difloxacin.
Exclusivity:	3 years

21CFR 520.645

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-082

Trade Name :	Heska™ Periodontal Disease Therapeutic		
Ingredients:	Doxycycline hyclate		
Sponsor:	Heska Corp.		
Approval Date:	11/19/97		
Status:	Prescription only		
Route:	Subgingivally to the periodontal pocket of the affected teeth		
Species:	Canine		
Drug Form:	Liquid		
Concentration:	8.5% doxycycline activity		
Indications:	For the treatment and control of periodontal disease in dogs.		
Patent Number:	4,938,763	Expiration date:	02/2008
	5,077,049		07/2009
	5,278,201		01/2011
	5,324,519		06/2011
Exclusivity:	5 years		

21CFR 522.778

Supplemental Approvals

NADA Number: 128-686

Trade Name :	BIO-COX® Type A Medicated Article
Ingredients:	Salinomycin sodium
Sponsor:	Hoffmann-La Roche, Inc.
Approval Date:	01/09/98
Status:	Over-the-counter
Route:	Oral
Species:	Avian (broiler, roaster, and replacement chickens; quail)
Drug Form:	Type A medicated article to make Type C medicated feeds
Concentration:	Type A: 60 g/lb..
Indications:	Broilers, roasters, replacement chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti*, and *E. mivati*. Quail: For the prevention of coccidiosis caused by *E. dispersa* and *E. lettyae.*
Tolerance:	There are no established tolerances for this ingredient.
Withdrawal:	Zero days.

This supplemental application provides for an alternate formulation, 60 g/lb, for the Type A medicated article in addition to the approved 30 g/lb product.

21CFR 558.550

NADA Number: 119-823 & 095-735

Trade Name :	Rumensin
Ingredients:	Monensin sodium
Sponsor:	Elanco Animal Health, a Division of Eli Lilly & Co.
Approval Date:	11/03/97
Status:	Over-the-counter
Route:	Oral
Species:	Bovine (pasture cattle)
Drug Form:	Type A medicated article to make Type C medicated feeds
Concentration:	810 mg/lb.
Indications:	For increased rate of weight gain.
Tolerance	21CFR556.420: a tolerance is established for negligible residues in edible tissues at 0.05 ppm.
Withdrawal	Zero days.

This supplemental application provides for transferring the data and information in NADA 119-823 into NADA 095-735, and withdrawing the approval of NADA 119-823.

21CFR 520.1448b (removed)

NADA Number: 140-929

Trade Name :	Micotil[â] 300
Ingredients:	Tilmicosin phosphate
Sponsor:	Elanco Animal Health, a Division of Eli Lilly & Co.
Approval Date:	12/23/97
Status:	Prescription only
Route:	Subcutaneous
Species:	Bovine (feedlot cattle)
Drug Form:	Liquid (solution)
Concentration:	300 mg/mL
Indications:	For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *P. haemolytica*.
Tolerance:	21CFR 556.735: a tolerance is established for residues of parent tilmicosin (marker residue) in liver (target tissue) of cattle at 1.2 ppm.
Withdrawal:	Cattle and pre-ruminating calves: 28 days
Patent Number:	4,820,695 Expiration date: 04/11/2006

This supplemental application provides for the deletion of the following statement from the label warnings: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal." However, since there is are no other data submitted to demonstrate the safety and effectiveness of the product in veal calves, this drug is not approved for use in veal calves and, as such, should not be promoted to use in this class of animals.

21CFR 522.2471

NADA Number: 128-409

Trade Name :	IVOMEC[â] Injection for Cattle and Swine
Ingredients:	Ivermectin
Sponsor:	Merial Limited
Approval Date:	12/19/97
Status:	Subcutaneous
Species:	Bovine, porcine, reindeer, American bison
Drug Form:	Liquid (solution)
Concentration:	10 mg/mL
Indications:	For the treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, sucking lice, and mange mites: CATTLE Gastrointestinal roundworms (adults and 4th stage larvae): *Ostertagia ostertagi* (including *inhibited O. ostertagi*), *O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Bunostomum phlebotomum, Nematodirus helvetianus* (adults only*), N. spathiger* (adults only). Lungworms (adults and 4th stage larvae): *Dictyocaulus viviparus*. Cattle Grubs (parasitic stages): *Hypoderma bovis, H. lineatum*. Sucking Lice: *Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*. Mites (Scabies): *Psoroptes ovis* (Syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*. Persistent Activity: IVOMEC Injection has been proved to effectively control infections and to protect cattle from re-infection with *Dictyocaulus viviparus* and *Ostertagia ostertagi* for 21 days after treatment; *Oesophagostomum radiatum, Haemonchus placei, Trichostrongylus axei, Cooperia punctata*, and *Cooperia oncophora* for 14 days after treatment.

NADA Number: 128-409, con't

SWINE

For the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice, and mange mites:

Gastrointestinal roundworms: Large roundworms, *Ascaris suum* (adults and 4th stage larvae); red stomach worm, *Hyostrongylus rubidus* (adults and 4th stage larvae); nodular worm, *Oesophagostomum* spp. (adults and 4th stage larvae); threadworm, *Strongyloides ransomi* (adults).

Somatic Roundworm Larvae: Threadworm, *Strongyloides ransomi* (somatic larvae). Sows must be treated at least seven days before farrowing to prevent infection in piglets.

Lungworms: *Metastrongylus* spp. (adults).

Lice: *Haematopinus suis*.

Mange Mites: *Sarcoptes scabiei* var. *suis*.

REINDEER

For the treatment and control of warbles (*Oedemagena tarandi*).

AMERICAN BISON

For the treatment and control of grubs (*Hypoderma bovis*).

Tolerance: 21CFR 556.344: The tolerance for the marker residue (22,23-dihydro-avermectin B_{1a}) of ivermectin in cattle is 100 ppb in liver (target tissue), in reindeer is 15 ppb in liver (target tissue), in swine is 20 ppb in liver (target tissue), and in American bison is 15 ppb in liver.

Withdrawal: Cattle: 35 days; swine: 18 days, reindeer: 56 days; American bison: 56 days

This supplemental application provides for an expansion of the label claims to include the use of the product in American bison for the treatment and control of grubs (*Hypoderma bovis*).

21CFR 522.1192 and 556.344

Change of Sponsor

NADA Numbers: 200-068, 200-137:

From Phoenix Pharmaceutical, Inc., to
Phoenix Scientific, Inc.,
3915 South 48th St. Terrace, P.O. Box 6457
St. Joseph, MO 64506-0457

NADA Numbers: 030-525, 035-825:

From DuPont Merck Pharmaceutical Co., to
Endo Pharmaceuticals, Inc.,
223 Wilmington West Chester Pike,
Chadds Ford, PA 19317. Drug labeler code: 060951

NADA Number: 010-886:

From PM Resources, Inc. to
Akzo Nobel Surface Chemistry AB,
Box 851, S-44485
Stenungsund, Sweden. Drug labeler code: 063765

Withdrawals

NADA Number: 038-247

Trade Name: Formica Breeder Premix H/Hygromycin B Type A medicated article
Sponsor: Mountaire Feeds, Inc.
Date: 02/12/98

NADA Number: 044-013

Trade Name: Formica Premix-T medicated/Tylosin Type A medicated article
Sponsor: Mountaire Feeds, Inc.
Date: 02/12/98

NADA Number: 065-273

Trade Name: Chloramphenicol capsules
Sponsor: Zenith Goldline Pharmaceuticals, Inc.
Date: 02/12/98

NADA Number: 065-456

Trade Name: Tetracycline HCl capsules
Sponsor: Zenith Goldline Pharmaceuticals, Inc.
Date: 02/12/98

NADA Number: 095-736

Trade Name: P.Q. Breeder Premix H/Hygromycin B Type A medicated article
Sponsor: Mountaire Feeds, Inc.
Date: 02/12/98

NADA Number: 098-895

Trade Name: Starbar GX-118
Sponsor: Wellmark International
Date: 02/12/98

NADA Number: 119-823

Trade Name: Rumineral Supplement Medicated
Sponsor: Elanco Animal Health, a Division of Eli Lilly & Co.
Date: 02/23/98

NADA Number: 137-138

Trade Name: Swine Premix W/Banminth/Pyrantel Tartrate Type A medicated article
Sponsor: Mountaire Feeds, Inc.
Date: 02/12/98

NADA Number: 139-239

Trade Name: Swine Guard-BN Premix/Banminth (pyrantel tartrate) Type A medicated article
Sponsor: Growmark, Inc.
Date: 02/12/98

Sponsors Address and Labeler Code

Rhone-Poulenc Chemicals, Ltd.,
P.O. Box 46, St. Andrews Rd.,
Avonmouth, Bristol BS11 9YF, England, UK.
Drug labeler code: 059258

Akzo Nobel Surface Chemistry AB,
Box 851, S-44485
Stenungsund, Sweden.
Drug labeler code: 063765

Re-designation of a Section of 21 CFR

Part 529 of the 21 CFR provides for codification of certain other dosage form new animal drugs. The regulations in part 526 of the 21 CFR provide for codification of intramammary dosage forms. Cephapirin sodium was inadvertently codified as 529.365. The animal drug regulations are amended to re-designate 529.365 as 526.365.

Correction to the November 1997 Update of the Green Book

ANADA 200-233: the correct number is 200-223.

Suitability Petition Actions

Number:	**97P-0473 CP1**
Sponsor:	Macleod Pharmaceuticals, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, Unibute Paste (phenylbutazone paste) which differs from the pioneer product, Butazolidin Paste, Mallinkrodt Veterinary, Inc., NADA 116-087 by the following characteristics: Unibute Paste: 20 g of phenylbutazone per 60 g of paste. Butazolidin Paste (pioneer): 12 g of phenylbutazone per 60 g of paste. The dosage (1-2 g of phenylbutazone/500 lbs body weight) is the same in both products.
Action:	Approved on 01/30/98.

Number:	**97P-0474 CP1**
Sponsor:	Macleod Pharmaceuticals, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, Uniprim Paste (trimethoprim and sulfadiazine) which differs from the pioneer product, Tribrissen 400 Oral Paste, Mallinkrodt Veterinary, Inc., NADA 131-918 by the following characteristics: Uniprim Paste: 56 mg of trimethoprim and 278 mg sulfadiazine per gram. Tribrissen Oral Paste (pioneer): 67 mg of trimethoprim and 333 mg sulfadiazine per gram. The dosage (30 mg/kg body weight) is the same in both products.
Action:	Approved on 01/30/98.